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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,781	02/04/2004	Jerry B. Gin	1375-0001.20	2376

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
09/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,781	GIN ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 25, 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-22,26,29,46,47,76,101,102 and 104-109* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-8, 12, 13, 26, 29, 46, 47, 101, 102 and 104-109* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed May 25, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 1-4, 6-8, 12, 13, 26, 46, 47 and 102-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (WO 99/06030, already of record) in view of Lin et al. (Journal of Controlled Release 2001, already of record) and Gohlke (US 2002/0054917, already of record).

Friedman et al. disclose oral herbal release tablets comprising a polymeric matrix material of ethyl cellulose. The tablet has a dissolution time of up to 120 minutes (Abstract). The term "tablet" encompasses troches and lozenges (page 4, lines 23-25). The compositions also have an herbal extracts and essential oil (page 3), which encompasses the limitation essential oils and constituents of essential oils. The herbal

extract itself may be a liquid (page 5, lines 25 and 26). The essential oil and extract comprise about 0.5 to about 40% percent weight per weight in the tablet (page 6, lines 7-9).

Lin et al. disclose the effects of micronized ethyl cellulose (EC) powders on the release rate of drugs. Ethyl cellulose is well-known and is often used as a rate-controlling membrane to modulate the drug release from dosage forms. The particle size of EC plays an important role in controlling drug release (page 322, col. 1, paragraph 2 to col. 2, paragraph 1). The viscosity of the EC powders used ranged from 6.2 to 84.9 cps (Table 1), encompassing "approximately 90 cP". Ethyl cellulose with larger particle size exhibit more rapid disintegration and leads to faster drug release (page 323, col. 2, last paragraph). The particle size of the EC used include 4.0, 4.6, 6.0, 167.5, 224.3 and 398.0 micro meters, encompassing claim 103. The reference differs from the instant claims insofar as it does not disclose the micronized EC powders are used in a soft lozenge with an essential oil.

The rate of release of the fragrance is dependent on the type of ethyl cellulose and the size of the ethyl cellulose used. It would have been obvious to use micronized ethyl cellulose as the ethyl cellulose in the compositions of Friedman et al. motivated by the desire to use ethyl cellulose that will give a slower rate of release than ethyl cellulose with a larger particle size and to obtain the desired rate of release of the fragrance as disclosed by Lin et al.

In regard to the amount and particle size of ethyl cellulose, the amount of ethyl cellulose and its particle size control the rate of release of the disclosed active. It would

have been obvious to one of ordinary skill in the art to have adjusted the amount of ethyl cellulose and used a certain particle size of micronized ethyl cellulose, such as about 20 microns as recited in the instant claims, in the compositions of the combined teachings of Alderman et al. and Lin et al. motivated by the desire to obtain the desired rate of release of the flavoring.

In regard to the specific percentages recited in the instant claims, see the indefinite rejection supra.

The combination of references differs from the instant claims insofar as they do not disclose the ethyl cellulose and essential oil are in a lozenge that is soft and has a pliable consistency.

Gohlke is used as a general teaching to show chewable lozenges are used to deliver active components to the oral cavity. Chewable lozenges are mucosal delivery devices (paragraph 0030). Lozenges enhance the benefits associated with absorption through the oral cavity because they are designed to be dissolved slowly in the mouth and they may also be chewable. Dosage forms that are chewable or that are appropriate for sucking can be additionally designed to encourage salivation. Such dosage forms include lozenges, particularly chewable lozenges, chewable tablets and chewable gums. The addition of natural or artificial flavoring also encourages retention of the dosage form within the mouth, particularly with children, so that there is greater transfer of the active components through the lining of the oral cavity and into the bloodstream and/or the lymphatic system (paragraph 0047). Chewable lozenges may also be chewed for prolonged periods of time (paragraph 0056). The compositions may

comprise fillers, sweeteners, colorants and sorbitol (paragraph 0048 and 0052), encompassing claims 26, 46 and 47. The reference differs from the instant claims insofar as it does not disclose the lozenges comprise ethyl cellulose in mixture with an essential oil.

It would have been obvious to have formulated a chewable lozenge comprising the compositions of the combined teachings of Alderman et al. and Lin et al. motivated by the desire to use a dosage form that enhances the benefits associated with absorption through the oral cavity because they are designed to be dissolved slowly in the mouth and can be chewed for prolonged periods of time as disclosed by Gohlke.

It would also have been obvious to have incorporated the ethyl cellulose/flavor composition of the combined teachings of Friedman et al. and Lin et al. into the chewable lozenges of Gohlke motivated by the desire to make a dosage form with a sustained release core that could continuously release flavoring encouraging the retention of the dosage form within the mouth particularly with children so that there is greater transfer of the active components through the lining of the oral cavity and into the bloodstream and/or the lymphatic system, as disclosed by Gohlke.

2) Claims 29 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (WO 99/06030, already of record) in view of Lin et al. (Journal of Controlled Release 2001) and Gohlke (US 2002/0054917) in further view of Ventouras (US 6,183,775, already of record).

Friedman et al., Lin et al. and Gohlke are discussed above. The combination of references differs from the instant claims insofar as they do not disclose the lozenge comprises a sweetener such as xylitol.

Ventouras discloses a controlled release lozenge having organoleptic properties. The lozenge comprises fillers including xylitol, mannitol and sorbitol (which are non sugar sweeteners); an insoluble film forming agent which is capable of forming an insoluble matrix including ethyl cellulose and a swellable polymer including xanthan gum and cellulose derivatives (see Abstract). Auxiliaries are used in the compositions including aromas, sweeteners, colorants, buffering agents and preservatives. The reference differs from the instant claims insofar as it does not disclose the compositions comprise a flavoring agent the amount recited.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used xylitol as the sweetener in the compositions of the combined teachings of Alderman et al., Lin et al. and Gohlke motivated by the desire to use a sweetener suitable for use in lozenges.

Declaration under 37 CFR 1.132 by Jerry Gin

Applicant has made the composition of Example I disclosed by Alderman et al. to show that the compositions of the reference are not the same as those of instant. This supports that the compositions of Alderman are not soft dosage forms.

Response to Declaration

The Declaration is not persuasive in regard to new rejections. Friedman et al. disclose lozenges in general but does not disclose a method of making a hard lozenge or a soft lozenge as encompassed by the instant invention. It does, however, suggest formulating the compositions into lozenges. Gohlke discloses why one of ordinary skill in the art would desire a chewable (soft) lozenge thereby providing the motivation of why one of ordinary skill in the art would want to make the compositions of Friedman et al. into soft lozenges.

Claims 1-4, 6-8, 26, 29, 46, 47 and 101-109 are rejected.

Claims 9-11, 14-22 and 76

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612